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Commissioner for Patents
Washington, D.C. 20231

Art Unit 1646

Re: U.S. Utility Patent Application
Appl. No. 09/340,690; Filed: June 29, 1999
For: **Human Tumor Necrosis Factor Receptor-Like 2**
Inventors: NI *et al.*
Our Ref: 1488.0770007/EKS/PAJ

Sir:

Transmitted herewith for appropriate action are the following documents:

1. Request by Applicants for Interference Under 37 C.F.R. §1.607 with Exhibits A through H; and

2. One return postcard.

It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier. In the event that extensions of time are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

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Enclosures

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: NI *et al.*	Confirmation No. 4231
Appl. No. 09/340,690	Art Unit: 1646
Filed: June 29, 1999	Examiner: Kemmerer, E.
For: **Human Tumor Necrosis Factor Receptor-Like 2**	Atty. Docket: 1488.0770007/EKS/PAJ

Request by Applicants for Interference Under 37 C.F.R. §1.607

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Under the provisions of 37 C.F.R. § 1.607, Applicants request to have an interference declared between the captioned application and two issued United States patents.

I. Identification of the Patents [37 C.F.R. § 1.607(a)(1)]

It is respectfully requested that an interference be declared between the captioned application and unexpired U.S. Patent Nos. 6,291,207 and 6,303,336. Applicants are simultaneously filing a Request for Interference Under 37 C.F.R. § 1.607 in Applicants' co-pending U.S. Application No. 08/741,095, requesting that an interference be declared between that application and U.S. Patent Nos. 6,291,207 and 6,303,336.

The basis for an interference between Applicants' above-captioned application and the two identified unexpired patents may be found in 37 C.F.R. § 1.601(i) (2001) which reads, in part, "[a]n interference may be declared between one or more pending applications and one or more unexpired patents naming different inventors when, in the opinion of an examiner, any

application and any unexpired patent contain claims for the same patentable invention." Thus, "37 CFR 1.601(i) includes the possibility that an interference may include more than one unexpired patent. . . . [I]f the examiner discovers two or more patents which are claiming the same invention as an application, interferences may be instituted between the application and the patents." M.P.E.P. § 2306, at 2300-12 (8th ed. 2001).

U.S. Patent No. 6,291,207 B1, [hereinafter "the '207 patent"] **(Exhibit A)** entitled "Herpes Virus Entry Receptor Protein," issued September 18, 2001, from U.S. Application No. 08/509,024, filed July 28, 1995, in the names of Patricia G. Spear and Rebecca I. Montgomery. The '207 patent contains claims directed to cDNA encoding full-length herpes virus entry receptor (HVEM), soluble HVEM and fragments thereof, as well as vectors containing the DNA, host cells containing the vectors and methods of making HVEM.

U.S. Patent No. 6,303,336 B1, [hereinafter "the '336 patent"] **(Exhibit B)** also entitled "Herpes Virus Entry Receptor Protein," issued October 16, 2001, from U.S. Application No. 09/333,279, filed June 15, 1999, which was a divisional of above-mentioned U.S. Application No. 08/509,024, filed July 28, 1995. The '336 patent contains claims directed to full length and soluble HVEM polypeptides encoded by specific cDNA, as well as host cells transformed with cDNA encoding HVEM and methods of making HVEM.

The specifications of both the '207 patent and the '336 patent are identical and disclose the isolation of a polynucleotide which encodes a human HVEM. In particular, using an iterative process to identify a human cDNA that enhances herpes simplex virus (HSV) entry into resistant CHO-K1 cells, the patentees isolated a cDNA that expressed a protein which had the desired phenotype. This clone was designated pBEC580. *See* the '207 patent at col. 7, lines 52-58. The nucleotide sequence of the cDNA insert of pBEC580 was determined and is shown in SEQ ID

NO:1 of the '207 and '336 patents, and the deduced amino acid sequence of human HVEM is shown in SEQ ID NO:2 of the '207 and '336 patents. *See* the '207 patent, col. 2, lines 49-52.

As filed, the nucleotide sequence of the cDNA insert of pBEC580 consisted of 1,719 nucleotides which coded for a 299 amino acid polypeptide.[1] *See* the '024 application, SEQ ID NOS:1 and 2 at pages 35-38. During prosecution of the '207 patent, however, the patentees filed a Supplemental Amendment on September 28, 1998, in which the patentees asserted that they

> have discovered that errors[2] were present in the sequence in original Figure 2 (original SEQ ID NOS:1 and 2). . . . Basis for . . . correction of the sequence in Figure 2 is found in the specification on page 32, wherein it is recited that the plasmid pBEC10[3], which contains the correct sequence of HVEM, was deposited with the American Type Culture Collection on July 28, 1995, the date of filing of the present application.

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[1]As disclosed in U.S. Application No. 08/509,024 [hereinafter "the '024 application"], HVEM "is an isolated and purified polypeptide of about 300 amino acid residues and comprises the amino acid residue sequence of SEQ ID NO:2." The '024 application at page 3. A copy of the '024 application as filed is attached as **Exhibit C**.

[2]A comparison of original SEQ ID NOS:1 and 2 as filed in the '024 application with corrected SEQ ID NOS:1 and 2 as issued in the '207 patent reveals that nucleotide errors resulted in an amino acid error at residue 56 of original SEQ ID NO:2, in a frame shift in the predicted soluble portion of HVEM such that amino acid residues 137 to 171 of original SEQ ID NO:2 were incorrect, and in a frame shift in the C-terminus such that amino acid residues 269 to 283 of original SEQ ID NO:2 were incorrect.

[3]According to the patentees, "[o]n page 16 of the specification, lines 11-19, it is disclosed that the sequence in the plasmid pBEC10 is also that shown in Figure 2, i.e., SEQ ID NO:1. Essentially, the HVEM sequence contained with pBEC580 was recloned into the vector pcDNA3, thereby generating the plasmid pBEC10. Thus, the HVEM sequence in pBEC580 and pBEC10 are the same." Prosecution History of the '207 patent, Paper No. 30 at page 5 **(Exhibit D)**.

Prosecution History of the '207 patent, Paper No. 21 at pages 2-3 **(Exhibit E)**. Substitute SEQ ID NOs:1 and 2, which are in the '207 and '336 patents as issued, code for a 1724 polynucleotide[4] and a 283 amino acid polypeptide,[5] respectively. *See* the '207 patent at col. 17 to col. 21.

The captioned application is a divisional of U.S. Application No. 08/741,095 [hereinafter "the '095 application"], filed October 30, 1996, which is a continuation-in-part of U.S. Application No. 08/464,595, U.S. Application No. 08/462,962, and U.S. Application No. 08/462,315, each of which was filed June 5, 1995, and each of which claim priority benefit to International Application No. PCT/US95/05058 [hereinafter "the '058 application"], filed April 27, 1995. In addition, the captioned application was filed with claims directed to, *inter alia*, isolated nucleic acid molecules encoding a human TR2 receptor, TR2 polypeptides, including the extracellular (soluble) portion and antigenic fragments thereof, vectors, host cells and recombinant methods for producing the same.

In reply to a Restriction Requirement in the parent '095 application, Applicants elected, with traverse, claims directed to isolated DNA encoding a TR2 receptor, recombinant vectors, methods of making a host cell and host cells in the '095 application and canceled claims directed to other embodiments of the invention. The captioned application was filed on June 29, 1999, as a divisional of the '095 application with claims directed to isolated TR2 proteins.

In the Second Preliminary Amendment and Submission of Sequence Listing filed in the captioned application on June 29, 1999, Applicants amended the specification to introduce

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[4]The open reading frame is from nucleotide position 294 to nucleotide position 1142 of SEQ ID NO:1 as issued as compared to nucleotide position 293 to nucleotide position 1189 of SEQ ID NO:1 as filed.

[5]Amino acid residues 1-38 of SEQ ID NO:2 represent the signal peptide. *See* the '207 patent at col. 2, lines 49-57.

subject matter from the '058 application. In particular, the Sequence Listing was amended by adding SEQ ID NOS:25 and 26, which are identical to SEQ ID NOS:1 and 2 of the '058 application, which had been incorporated by reference into the present application at the time the present application was filed. SEQ ID NO:25 shows a 881[6] base pair polynucleotide which encodes the 283 amino acid polypeptide shown in SEQ ID NO:26.[7] The presently pending claims are directed to, *inter alia*, an isolated protein which comprises the full length, mature and soluble polypeptides of SEQ ID NO:26 and antigenic fragments thereof. A copy of the presently pending claims is attached as **Exhibit F.**

Although the polypeptides disclosed in Applicants' application and in the '207 and '336 patents have different names, *i.e.* TR2 and HVEM, the amino acid sequence of SEQ ID NO:26 in Applicants' application and SEQ ID NO:2 in the '207 and '336 patents are identical. *See* Amino Acid Sequence Alignment **(Exhibit G)**. In addition, the nucleotide sequences of the open reading frames which encode for the claimed polypeptides differ by only one nucleotide, which results in a silent error. *See* Nucleotide Sequence Alignment **(Exhibit H)**.

II. Presentation of a Proposed Count [37 C.F.R. § 1.607(a)(2)]

Applicants propose the following one count with three alternative embodiments for purposes of interference:

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[6]The open reading frame is from nucleotide position 9 to nucleotide position 857 of SEQ ID NO:25.

[7]Amino acid residues -38 to -1 of SEQ ID NO:26 represent the signal peptide, amino acid residues 1 to 162 of SEQ ID NO:26 represent the soluble or extracellular domain of the polypeptide, and amino acid residues 1 to 245 of SEQ ID NO:26 represent the mature polypeptide.

[A] An isolated polynucleotide comprising at least 50 contiguous nucleotides of the HVEM cDNA contained within the plasmid pBEC580,[8] designated as ATCC No. 97236;

OR

[B] An isolated protein comprising 30 contiguous amino acids of the polypeptide consisting of the amino acid sequence of SEQ ID NO:26[9], wherein said 30 contiguous amino acids comprises an antigenic determinant for the polypeptide consisting of the amino acid sequence of SEQ ID NO:26;

OR

[C] An isolated and purified polypeptide encoded by a cDNA contained within the plasmid pBL58[10] (ATCC No. 97237), wherein said cDNA comprises a nucleotide sequence which encodes soluble HVEM and does not comprise a nucleotide sequence which encodes rabbit immunoglobulin heavy chain.

Proposed Count 1 has been crafted in the three alternative embodiments because the three embodiments are patentably *indistinct*, and the three embodiments encompass the subject matter that is claimed in the captioned application and the '207 and '336 patents. Specifically, the proposed count includes claim 23 from the '207 patent [A], claim 187 from the captioned application [B] and claim 6 from the '336 patent [C]. *See, e.g., Orikasa v. Oonishi*, 10 USPQ2d

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[8]This plasmid contains a cDNA sequence encoding for human HVEM. The nucleotide sequence of the cDNA insert of pBEC580 and deduced amino acid sequence is shown in SEQ ID NOS:1 and 2 and FIGS. 2A-2B of the '207 and '336 patents **(Exhibits A and B)**.

[9]SEQ ID NO:26 of the captioned application is identical to SEQ ID NO:2 from the '058 application and shows a 283 amino acid polypeptide.

[10]"The plasmid pBL58 contains DNA encoding the soluble portion of HVEM (SEQ ID NO:6 is the DNA sequence and SEQ ID NO:7 is the amino acid sequence of this portion of HVEM) fused to an Fc molecule as disclosed in Figures 7 and 8 and on pages 22 and 23 of the specification." Prosecution History of the '207 patent, Paper No. 30 at page 5. In addition, the patentees asserted that "[u]pon a reading of the description of Figure 8 on page 6, and upon inspection of the actual Figure, it is clear that the portion of the human HVEM polynucleotide in pBL58 which encodes HVEM, but does not encode any immunoglobulin sequences encodes amino acids 1-185 of human HVEM." *Id.* at page 4.

1996, 2000 n.10 (B.P.A.I. 1989) (an interference count may be formed as to include, in the alternative, the claimed subject matter of the opposing parties, which together constitutes the same patentable invention). This proposed count, which relates to TR2/HVEM DNA and protein, encompasses all patentable claims which correspond to the count.

As noted above, a Restriction Requirement was issued on October 2, 1997 in the '095 application, wherein Group I was drawn to an isolated DNA/recombinant vector/method of making a host cell/host cell and Group II was drawn to an isolated polypeptide. However, the Examiner's *prima facie* showing for a restriction requirement may be rebutted by appropriate showings or evidence by Applicants. *See* M.P.E.P. § 803, at 800-4; *see also*, *Irikura v. Petersen*, 18 USPQ2d 1362, 1366 (B.P.A.I. 1990). Moreover, it is well established legally that "[d]ecisions of a primary examiner during *ex parte* prosecution are likewise not binding on the Board of Patent Appeals and Interferences in *inter partes* proceedings." *Okada v. Hitotsumachi*, 16 USPQ2d 1789, 1790-91 (Comm'r Pat. & Trademarks 1990) (citations omitted). Accordingly, it is respectfully submitted that the three alternative embodiments of the proposed count define the same patentable invention for the reasons provided below.

The term "same patentable invention" is defined at 37 C.F.R. § 1.601(n) in the following manner: "Invention 'A' is the *same patentable invention* as an invention 'B' when invention 'A' is the same as (35 U.S.C. 102) or is obvious (35 U.S.C. 103) in view of invention 'B' assuming invention 'B' is prior art with respect to invention 'A.'" By the definition of "same patentable invention" provided in 37 C.F.R. § 1.601(n), the alternative embodiments [A], [B] and [C] of the proposed count are the same patentable invention as they are either anticipated or obvious in view of each other.

The subject matter of the invention claimed in the '207 and '336 patents and the captioned application is identical; the two patents and Applicants' pending application are merely claiming various obvious embodiments gleaned from the cloning of TR2/HVEM. In particular, the polynucleotides disclosed by Applicants and the patentees are nearly identical, and both Applicants and the patentees are claiming polypeptides with identical amino acid sequences. In addition, the claimed polypeptides are defined in terms of the DNA which encodes it. For example, claim 1 of the '207 patent recites:

> An isolated polynucleotide comprising a cDNA contained within the plasmid pBEC580, designated as ATCC No. 97236.

The '207 patent, col. 29, lines 13-15. Claim 1 of the '336 patent recites:

> An isolated and purified polypeptide of about 300 amino acid residues, wherein said polypeptide is encoded by a cDNA contained within the plasmid pBEC580, designated as ATCC No. 97236.

The '336 patent, col. 29, lines 15-18.

Applicants submit that if one skilled in the art had a protein defined by the cDNA sequence encoding the protein, then one would know the sequence of the cDNA and one could clone the cDNA encoding the protein. In addition, if one had a cDNA clone and knew its open reading frame, including the initiation codon and the termination codon, then one could predict the amino acid sequence of the protein encoded by the open reading frame. That is, claim 1 of the '336 patent is merely an obvious variation of claim 1 of the '207 patent, as once the DNA sequence of the cDNA insert contained within the plasmid pBEC580 is known, the amino acid sequence can then be deduced. In the present case, the '207 and '336 patents' claims are the same patentable invention as Proposed Count 1 *because the claims are directed to proteins that are defined by the cDNA sequences encoding the proteins, not the amino acid sequences.*

In view of the above, Applicants respectfully submit that the three alternative embodiments of the present invention are drawn to the same patentable invention, and the proposed count should be the count of the interference.

III. Identification of At Least One Claim in Each of the Two Patents Corresponding to the Proposed Count [37 C.F.R. § 1.607(a)(3)]

A. Claims in U.S. Patent No. 6,291,207

All of the claims of the '207 patent (claims 1-23) correspond, either exactly or substantially, to the proposed count. In particular, claim 1 of the '207 patent recites "[a]n isolated polynucleotide comprising a cDNA contained within the plasmid pBEC580, designated as ATCC No. 97236." Claim 1 does not correspond exactly to alternative [A] of the proposed count. However, claim 1 defines the same patentable invention as the proposed count and should be designated as corresponding to the count.

Claim 2 of the '207 patent is dependent on claim 1 and requires that the cDNA is the sequence of SEQ ID NO:1 from nucleotide position 294 to nucleotide position 1142. This claim does not correspond exactly to alternative [A] of the count but defines the same patentable invention as the proposed count and should be designated as corresponding to the count.

Claim 3 of the '207 patent is dependent on claim 1 and relates to an expression vector comprising the polynucleotide of claim 1. This claim does not correspond exactly to alternative [A] of the count but defines the same patentable invention as the proposed count and should be designated as corresponding to the count.

Claim 4 of the '207 patent is dependent on claim 3 and relates to an expression vector which further comprises an enhancer-promoter operatively linked to said polynucleotide. This

claim does not correspond exactly to alternative [A] of the count but defines the same patentable invention as the proposed count and should be designated as corresponding to the count.

Claim 5 of the '207 patent is dependent on claim 3 and relates to an expression vector wherein the polynucleotide consists of the nucleotide sequence of SEQ ID NO:1 from nucleotide position 294 to nucleotide position 1142. This claim does not correspond exactly to alternative [A] of the count but defines the same patentable invention as the proposed count and should be designated as corresponding to the count.

Claim 6 of the '207 patent is dependent on claim 3 and relates to a host cell transformed with an expression vector. This claim does not correspond exactly to alternative [A] of the count but defines the same patentable invention as the proposed count and should be designated as corresponding to the count.

Claim 7 of the '207 patent is dependent on claim 6 and relates to a mammalian host cell. This claim does not correspond exactly to alternative [A] of the count but defines the same patentable invention as the proposed count and should be designated as corresponding to the count.

Claim 8 of the '207 patent is dependent on claim 7 and relates to an ovarian host cell. This claim does not correspond exactly to alternative [A] of the count but defines the same patentable invention as the proposed count and should be designated as corresponding to the count.

Claim 9 of the '207 patent is dependent on claim 8 and relates to ovarian host cells selected from the group consisting of CHO-A3, CHO-A12, CHO-B3, CHO-B9 and CHO-B11. This claim does not correspond exactly to alternative [A] of the count but defines the same

patentable invention as the proposed count and should be designated as corresponding to the count.

Claim 10 of the '207 patent is dependent on claim 6 and relates to a bacterial host cell. This claim does not correspond exactly to alternative [A] of the count but defines the same patentable invention as the proposed count and should be designated as corresponding to the count.

Claim 11 of the '207 patent is dependent on claim 3 and relates to a method of making HVEM which comprises transforming a host cell with an expression vector, maintaining the transformed cell for a period of time sufficient for expression of HVEM, and recovering HVEM from the cell. This claim does not correspond exactly to alternative [A] of the count but defines the same patentable invention as the proposed count and should be designated as corresponding to the count.

Claim 12 of the '207 patent is dependent on claim 11 and requires that the host cell be a eukaryotic cell. This claim does not correspond exactly to alternative [A] of the count but defines the same patentable invention as the proposed count and should be designated as corresponding to the count.

Claim 13 of the '207 patent is dependent on claim 12 and requires that the eukaryotic cell be an ovarian cell. This claim does not correspond exactly to alternative [A] of the count but defines the same patentable invention as the proposed count and should be designated as corresponding to the count.

Claim 14 of the '207 patent is dependent on claim 11 and requires that the HVEM be encoded by SEQ ID NO:1 from nucleotide position 294 to nucleotide position 1142. This claim

does not correspond exactly to alternative [A] of the count but defines the same patentable invention as the proposed count and should be designated as corresponding to the count.

Claim 15 of the '207 patent recites "[a]n isolated polynucleotide complementary to a cDNA contained within the plasmid pBEC580, designated as ATCC No. 97236." This claim does not correspond exactly to alternative [A] of the count but defines the same patentable invention as the proposed count and should be designated as corresponding to the count.

Claim 16 of the '207 patent is dependent on claim 15 and requires that the polynucleotide be DNA. This claim does not correspond exactly to alternative [A] of the count but defines the same patentable invention as the proposed count and should be designated as corresponding to the count.

Claim 17 of the '207 patent is dependent on claim 15 and requires that the polynucleotide be RNA. This claim does not correspond exactly to alternative [A] of the count but defines the same patentable invention as the proposed count and should be designated as corresponding to the count.

Claim 18 of the '207 patent recites "[a] plasmid selected from the group consisting of pBEC10 (ATCC No. 97235), pBEC580 (ATCC No. 97236) and pBL58 (ATCC No. 97237)." This claim does not correspond exactly to alternative [A] of the count but defines the same patentable invention as the proposed count and should be designated as corresponding to the count.

Claim 19 of the '207 patent recites "[a]n isolated polynucleotide contained within the plasmid pBL58 (ATCC No. 97237), wherein said polynucleotide comprises nucleic acid encoding HVEM and further comprises a rabbit immunoglobulin heavy chain nucleotide sequence." This claim does not correspond exactly to alternative [A] of the count but defines the

same patentable invention as the proposed count and should be designated as corresponding to the count.

Claim 20 of the '207 patent recites "[a]n isolated polynucleotide comprising a cDNA contained within the plasmid pBL58 (ATCC No. 97237), wherein said cDNA comprises a nucleotide sequence which encodes soluble HVEM and does not comprise a nucleotide sequence which encodes rabbit immunoglobulin heavy chain." This claim does not correspond exactly to alternative [A] of the count but defines the same patentable invention as the proposed count and should be designated as corresponding to the count.

Claim 21 of the '207 patent recites "[a]n isolated polynucleotide comprising a cDNA contained within the plasmid pBL58 (ATCC No. 97237), wherein said cDNA encodes amino acids 1-185 of human HVEM." This claim does not correspond exactly to alternative [A] of the count but defines the same patentable invention as the proposed count and should be designated as corresponding to the count.

Claim 22 of the '207 patent recites "[a]n isolated polynucleotide comprising a nucleotide sequence which a) encodes soluble HVEM, wherein said soluble HVEM comprises an amino acid sequence encoded by a cDNA contained within the plasmid pBL58 (ATCC No. 97237); and b) does not encode a rabbit immunoglobulin heavy chain amino acid sequence." This claim does not correspond exactly to alternative [A] of the count but defines the same patentable invention as the proposed count and should be designated as corresponding to the count.

Claim 23 of the '207 patent recites "[a]n isolated polynucleotide comprising at least 50 contiguous nucleotides of the HVEM cDNA contained within the plasmid pBEC580, designated as ATCC No. 97236." This claim corresponds exactly to alternative [A] of the count and should be designated as corresponding to the count.

B. Claims in U.S. Patent No. 6,303,336

All of the claims of the '336 patent (claims 1-26) correspond, either exactly or substantially, to the proposed count. In particular, claim 1 of the '336 patent recites "[a]n isolated and purified polypeptide of about 300 amino acid residues, wherein said polypeptide is encoded by a cDNA contained within the plasmid pBEC580, designated as ATCC No. 97236." This claim does not correspond exactly to alternative [C] of the count but defines the same patentable invention as the proposed count and should be designated as corresponding to the count.

Claim 2 of the '336 patent recites "[a] recombinant human HVEM polypeptide, wherein said polypeptide is encoded by a cDNA contained within the plasmid pBEC580, designated as ATCC No. 97236." This claim does not correspond exactly to alternative [C] of the count but defines the same patentable invention as the proposed count and should be designated as corresponding to the count.

Claim 3 of the '336 is dependent on claim 2 and requires that the cDNA be the sequence of SEQ ID NO:1 from nucleotide position 294 to nucleotide position 1142. This claim does not correspond exactly to alternative [C] of the count but defines the same patentable invention as the proposed count and should be designated as corresponding to the count.

Claim 4 of the '336 patent recites "[a] recombinant human HVEM made by the process of transforming a host cell with an expression vector comprising a cDNA contained within the plasmid pBEC580, designated as ATCC No. 97236, maintaining the transformed cell for a period of time sufficient for expression of said HVEM, and recovering said HVEM from said cell." This claim does not correspond exactly to alternative [C] of the count but defines the same patentable invention as the proposed count and should be designated as corresponding to the count.

Claim 5 of the '336 patent recites "[a]n isolated and purified polypeptide encoded by a cDNA contained within the plasmid pBL58 (ATCC No. 97237), wherein said polypeptide comprises a rabbit immunoglobulin heavy chain amino acid sequence." This claim does not correspond exactly to alternative [C] of the count but defines the same patentable invention as the proposed count and should be designated as corresponding to the count.

Claim 6 of the '336 patent recites "[a]n isolated and purified polypeptide encoded by a cDNA contained within the plasmid pBL58 (ATCC No. 97237), wherein said cDNA comprises a nucleotide sequence which encodes soluble HVEM and does not comprise a nucleotide sequence which encodes rabbit immunoglobulin heavy chain." This claim corresponds exactly to alternative [C] of the count and should be designated as corresponding to the count.

Claim 7 of the '336 patent recites "[a]n isolated and purified polypeptide encoded by a cDNA contained within the plasmid pBL58 (ATCC No. 97237), wherein said polypeptide comprises amino acids 1-185 of human HVEM." This claim does not correspond exactly to alternative [C] of the count but defines the same patentable invention as the proposed count and should be designated as corresponding to the count.

Claim 8 of the '336 patent recites "[a]n isolated and purified polypeptide comprising soluble HVEM, wherein said soluble HVEM comprises an amino acid sequence encoded by a cDNA contained within the plasmid pBL58 (ATCC No. 97237), and further wherein said soluble HVEM does not comprise a rabbit immunoglobulin heavy chain amino acid sequence." This claim does not correspond exactly to alternative [C] of the count but defines the same patentable invention as the proposed count and should be designated as corresponding to the count.

Claim 9 of the '336 patent recites "[a] cell transformed with a nucleic acid encoding a recombinant human HVEM polypeptide, wherein said polypeptide is encoded by a cDNA

contained within the plasmid pBEC580, designated as ATCC NO. 97236." This claim does not correspond exactly to alternative [C] of the count but defines the same patentable invention as the proposed count and should be designated as corresponding to the count.

Claim 10 of the '336 patent is dependent on claim 9 and requires that the cell be a mammalian cell. This claim does not correspond exactly to alternative [C] of the count but defines the same patentable invention as the proposed count and should be designated as corresponding to the count.

Claim 11 of the '336 patent is dependent on claim 10 and requires that the cell be an ovarian cell. This claim does not correspond exactly to alternative [C] of the count but defines the same patentable invention as the proposed count and should be designated as corresponding to the count.

Claim 12 of the '336 patent is dependent on claim 11 and requires that the ovarian cell be selected from the group consisting of CHO-A3, CHO-A12, CHO-B3, CHO-B9 and CHO-B11. This claim does not correspond exactly to alternative [C] of the count but defines the same patentable invention as the proposed count and should be designated as corresponding to the count.

Claim 13 of the '336 patent is dependent on claim 9 and requires that the cell be a bacterial cell. This claim does not correspond exactly to alternative [C] of the count but defines the same patentable invention as the proposed count and should be designated as corresponding to the count.

Claim 14 of the '336 patent recites "[a] method of making a recombinant human HVEM, said method comprising transforming a host cell with an expression vector comprising a cDNA contained within the plasmid pBEC580, designated as ATCC No. 97236, maintaining the

transformed cell for a period of time sufficient for expression of said HVEM, and recovering said HVEM from said cell." This claim does not correspond exactly to alternative [C] of the count but defines the same patentable invention as the proposed count and should be designated as corresponding to the count.

Claim 15 of the '336 patent is dependent on claim 14 and requires that the host cell be a eukaryotic cell. This claim does not correspond exactly to alternative [C] of the count but defines the same patentable invention as the proposed count and should be designated as corresponding to the count.

Claim 16 of the '336 patent is dependent on claim 15 and requires that the eukaryotic cell be an ovarian cell. This claim does not correspond exactly to alternative [C] of the count but defines the same patentable invention as the proposed count and should be designated as corresponding to the count.

Claim 17 of the '336 patent is dependent on claim 16 and relates to HVEM which is encoded by SEQ ID NO:1 from nucleotide position 294 to nucleotide position 1142, wherein SEQ ID NO:1 is contained with the plasmid pBEC580, designated as ATCC No. 97236. This claim does not correspond exactly to alternative [C] of the count but defines the same patentable invention as the proposed count and should be designated as corresponding to the count.

Claim 18 of the '336 patent recites "[a] cell transformed with a nucleic acid encoding a polypeptide, said polypeptide comprising soluble HVEM, wherein said soluble HVEM comprises an amino acid sequence encoded by a cDNA contained within the plasmid pBL58 (ATCC No. 97237), and further wherein said soluble HVEM does not comprise a rabbit immunoglobulin heavy chain amino acid sequence." This claim does not correspond exactly to

alternative [C] of the count but defines the same patentable invention as the proposed count and should be designated as corresponding to the count.

Claim 19 of the '336 patent is dependent on claim 18 and requires that the cell be a mammalian cell. This claim does not correspond exactly to alternative [C] of the count but defines the same patentable invention as the proposed count and should be designated as corresponding to the count.

Claim 20 of the '336 patent is dependent on claim 19 and requires that the cell be an ovarian cell. This claim does not correspond exactly to alternative [C] of the count but defines the same patentable invention as the proposed count and should be designated as corresponding to the count.

Claim 21 of the '336 patent is dependent on claim 20 and requires that the ovarian cell be selected from the group consisting of CHO-A3, CHO-A12, CHO-B3, CHO-B9 and CHO-B11. This claim does not correspond exactly to alternative [C] of the count but defines the same patentable invention as the proposed count and should be designated as corresponding to the count.

Claim 22 of the '336 patent is dependent on claim 18 and requires that the cell be a bacterial cell. This claim does not correspond exactly to alternative [C] of the count but defines the same patentable invention as the proposed count and should be designated as corresponding to the count.

Claim 23 of the '336 patent recites "[a] method of making a soluble human HVEM, said method comprising transforming a host cell with an expression vector comprising a cDNA contained within the plasmid pBL58, designated as ATCC No. 97237, maintaining the transformed cell for a period of time sufficient for expression of said HVEM, and recovering said

HVEM from said cell." This claim does not correspond exactly to alternative [C] of the count but defines the same patentable invention as the proposed count and should be designated as corresponding to the count.

Claim 24 of the '336 patent is dependent on claim 23 and requires that the host cell be a eukaryotic cell. This claim does not correspond exactly to alternative [C] of the count but defines the same patentable invention as the proposed count and should be designated as corresponding to the count.

Claim 25 of the '336 patent is dependent on claim 24 and requires that the eukaryotic cell be an ovarian cell. This claim does not correspond exactly to alternative [C] of the count but defines the same patentable invention as the proposed count and should be designated as corresponding to the count.

Claim 26 of the '336 patent is dependent on claim 23 and relates to soluble HVEM which comprises an amino acid sequence encoded by a cDNA contained within the plasmid pBL58 (ATCC No. 97237), and further wherein the soluble HVEM does not comprise a rabbit immunoglobulin heavy chain amino acid sequence. This claim does not correspond exactly to alternative [C] of the count but defines the same patentable invention as the proposed count and should be designated as corresponding to the count.

IV. Presentation or Identification of Claims Corresponding to the Proposed Count [37 C.F.R. § 1.607(a)(4)]

Claims 27-38, 45-50, 57-62, 81-86 and 175-196 are pending in the captioned application. A clean copy of the pending claims is attached as **Exhibit F**. Claims 27-38, 81-86 and 187-196

correspond, either exactly or substantially, to the proposed count, whereas claims 45-50, 57-62 and 175-186[11] do not correspond to the count.

Claim 27 of the captioned application recites "[a]n isolated Human Tumor Necrosis Factor Receptor-Like 2 protein comprising amino acids 1 to 245 of SEQ ID NO:26.[12]" This claim does not correspond exactly to alternative [B] of the count but defines the same patentable invention as the proposed count and should be designated as corresponding to the count, as a polypeptide comprising amino acids 1 to 245 of SEQ ID NO:26 would clearly anticipate a polypeptide comprising 30 contiguous amino acids of the amino acid sequence of SEQ ID NO:26 which comprises an antigenic determinant as recited in the proposed count, and knowledge of 30 contiguous amino acids of the amino acid sequence of SEQ ID NO:26 necessarily requires knowledge of the amino acid sequence of SEQ ID NO:26, which includes amino acids 1 to 245. Similar reasoning applies in explaining why claims 28, 29, 33-35, 81-83, 188, 192 and 193 correspond to the proposed count.

Claim 28 of the captioned application is dependent on claim 27 and relates to an isolated protein which comprises amino acids -38 to 245 of SEQ ID NO:26[13]. This claim does not correspond exactly to alternative [B] of the count but defines the same patentable invention as the proposed count and should be designated as corresponding to the count.

Claim 29 of the captioned application is dependent on claim 27 and relates to an isolated protein which is produced by a recombinant host cell. This claim does not correspond exactly

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[11]These claims are directed to splice variants of the TR2 receptor.

[12]Amino acid residues from about 1 to about 245 of SEQ ID NO:26 constitute the soluble, transmembrane and intracellular domains of the TR2 receptor.

[13]Amino acid residues from about -38 to about 245 of SEQ ID NO:26 constitute the leader sequence as well as the soluble, transmembrane and intracellular domains of the TR2 receptor.

to alternative [B] of the count but defines the same patentable invention as the proposed count and should be designated as corresponding to the count.

Claim 30 of the captioned application is dependent on claim 27 and relates to an isolated protein which comprises a heterologous polypeptide. This claim does not correspond exactly to alternative [B] of the count but defines the same patentable invention as the proposed count and should be designated as corresponding to the count since claim 27 defines the same patentable invention as the proposed count and a heterologous polypeptide comprising the isolated protein of claim 27 would be obvious in view of the knowledge of the isolated protein of claim 27, and the isolated protein of claim 27 would be rendered obvious in view of the knowledge of a heterologous polypeptide comprising the polypeptide. Similar reasoning applies in explaining why claims 30-32, 36-38, 84-86, 189-191 and 194-196 correspond to the proposed count.

Claim 31 of the captioned application is dependent on claim 30 and relates to an isolated protein wherein the heterologous polypeptide comprises the Fc portion of an antibody molecule. This claim does not correspond exactly to alternative [B] of the count but defines the same patentable invention as the proposed count and should be designated as corresponding to the count.

Claim 32 of the captioned application is dependent on claim 27 and relates to a composition comprising the isolated protein of claim 27 and a carrier. This claim does not correspond exactly to alternative [B] of the count but defines the same patentable invention as the proposed count and should be designated as corresponding to the count.

Claim 33 of the captioned application recites "[a]n isolated protein comprising 30 contiguous amino acids of the complete amino acid sequence encoded by the cDNA clone contained in ATCC Deposit No. 97059, wherein said 30 contiguous amino acids comprises an

antigenic determinant for the polypeptide consisting of the amino acid sequence encoded by the cDNA clone contained in ATCC Deposit No. 97059." This claim does not correspond exactly to alternative [B] of the count but defines the same patentable invention as the proposed count and should be designated as corresponding to the count.

Claim 34 of the captioned application is dependent on claim 33 and relates to an isolated protein which comprises the complete amino acid sequence encoded by the cDNA clone contained in ATCC Deposit No. 97059. This claim does not correspond exactly to alternative [B] of the count but defines the same patentable invention as the proposed count and should be designated as corresponding to the count.

Claim 35 of the captioned application is dependent on claim 33 and relates to an isolated protein which is produced by a recombinant host cell. This claim does not correspond exactly to alternative [B] of the count but defines the same patentable invention as the proposed count and should be designated as corresponding to the count.

Claim 36 of the captioned application is dependent on claim 33 and relates to an isolated protein which comprises a heterologous polypeptide. This claim does not correspond exactly to alternative [B] of the count but defines the same patentable invention as the proposed count and should be designated as corresponding to the count.

Claim 37 of the captioned application is dependent on claim 36 and relates to an isolated protein wherein the heterologous polypeptide comprises the Fc portion of an antibody molecule. This claim does not correspond exactly to alternative [B] of the count but defines the same patentable invention as the proposed count and should be designated as corresponding to the count.

Claim 38 of the captioned application is dependent on claim 33 and relates to a composition comprising the isolated protein of claim 33 and a carrier. This claim does not correspond exactly to alternative [B] of the count but defines the same patentable invention as the proposed count and should be designated as corresponding to the count.

Claim 81 of the captioned application recites "[a]n isolated Human Tumor Necrosis Factor Receptor-Like 2 protein comprising amino acids 1 to 162 of SEQ ID NO:26.[14]" This claim does not correspond exactly to alternative [B] of the count but defines the same patentable invention as the proposed count and should be designated as corresponding to the count.

Claim 82 of the captioned application is dependent on claim 81 and relates to an isolated protein which comprises amino acids -38 to 162 of SEQ ID NO:26[15]. This claim does not correspond exactly to alternative [B] of the count but defines the same patentable invention as the proposed count and should be designated as corresponding to the count.

Claim 83 of the captioned application is dependent on claim 81 and relates to an isolated protein which is produced by a recombinant host cell. This claim does not correspond exactly to alternative [B] of the count but defines the same patentable invention as the proposed count and should be designated as corresponding to the count.

Claim 84 of the captioned application is dependent on claim 81 and relates to an isolated protein which comprises a heterologous polypeptide. This claim does not correspond exactly to alternative [B] of the count but defines the same patentable invention as the proposed count and should be designated as corresponding to the count.

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[14]Amino acid residues from about 1 to about 162 of SEQ ID NO:26 constitute the soluble domain of the TR2 receptor.

[15]Amino acid residues from about -38 to about 162 of SEQ ID NO:26 constitute the leader sequence as well as the soluble domain of the TR2 receptor.

Claim 85 of the captioned application is dependent on claim 84 and relates to an isolated protein wherein the heterologous polypeptide comprises the Fc portion of an antibody molecule. This claim does not correspond exactly to alternative [B] of the count but defines the same patentable invention as the proposed count and should be designated as corresponding to the count.

Claim 86 of the captioned application is dependent on claim 81 and relates to a composition comprising the isolated protein of claim 81 and a carrier. This claim does not correspond exactly to alternative [B] of the count but defines the same patentable invention as the proposed count and should be designated as corresponding to the count.

Claim 187 of the captioned application recites "[a]n isolated protein comprising 30 contiguous amino acids of the polypeptide consisting of the amino acid sequence of SEQ ID NO: 26, wherein said 30 contiguous amino acids comprises an antigenic determinant for the polypeptide consisting of the amino acid sequence of SEQ ID NO: 26." This claim corresponds exactly to alternative [B] of the count and should be designated as corresponding to the count.

Claim 188 of the captioned application is dependent on claim 187 and relates to an isolated protein which is produced by a recombinant host cell. This claim does not correspond exactly to alternative [B] of the count but defines the same patentable invention as the proposed count and should be designated as corresponding to the count.

Claim 189 of the captioned application is dependent on claim 187 and relates to an isolated protein which comprises a heterologous polypeptide. This claim does not correspond exactly to alternative [B] of the count but defines the same patentable invention as the proposed count and should be designated as corresponding to the count.

Claim 190 of the captioned application is dependent on claim 189 and relates to an isolated protein wherein the heterologous polypeptide comprises the Fc portion of an antibody molecule. This claim does not correspond exactly to alternative [B] of the count but defines the same patentable invention as the proposed count and should be designated as corresponding to the count.

Claim 191 of the captioned application is dependent on claim 187 and relates to a composition comprising the isolated protein of claim 187 and a carrier. This claim does not correspond exactly to alternative [B] of the count but defines the same patentable invention as the proposed count and should be designated as corresponding to the count.

Claim 192 of the captioned application recites "[a]n isolated protein comprising the mature amino acid sequence encoded by the cDNA clone contained in ATCC Deposit No. 97059." This claim does not correspond exactly to alternative [B] of the count but defines the same patentable invention as the proposed count and should be designated as corresponding to the count.

Claim 193 of the captioned application is dependent on claim 192 and relates to an isolated protein which is produced by a recombinant host cell. This claim does not correspond exactly to alternative [B] of the count but defines the same patentable invention as the proposed count and should be designated as corresponding to the count.

Claim 194 of the captioned application is dependent on claim 192 and relates to an isolated protein which comprises a heterologous polypeptide. This claim does not correspond exactly to alternative [B] of the count but defines the same patentable invention as the proposed count and should be designated as corresponding to the count.

Claim 195 of the captioned application is dependent on claim 194 and relates to an isolated protein wherein the heterologous polypeptide comprises the Fc portion of an antibody molecule. This claim does not correspond exactly to alternative [B] of the count but defines the same patentable invention as the proposed count and should be designated as corresponding to the count.

Claim 196 of the captioned application is dependent on claim 192 and relates to a composition comprising the isolated protein of claim 192 and a carrier. This claim does not correspond exactly to alternative [B] of the count but defines the same patentable invention as the proposed count and should be designated as corresponding to the count.

V. Application of Terms of Claims Identified as Corresponding to the Count and Not Previously in the Application to the Disclosure of U.S. Appl. No. 09/340,690 [37 C.F.R. § 1.607(a)(5)]

37 C.F.R. § 1.607(a)(5) requires that an applicant apply "the terms of any application claim, (i) [i]dentified as corresponding to the count, and (ii) [n]ot previously in the application to the disclosure of the application." Claims 27-38, 81-86 and 187-196, which have been identified as corresponding either exactly or substantially to alternative [B] of the proposed count, were previously pending in the application prior to the filing of this Request for Interference. Accordingly, application of the terms of the claims to the disclosure of the application is not required.

VI. Meeting the Requirements of 35 U.S.C. § 135(b) [37 C.F.R. § 1.607(a)(6)]

A. 35 U.S.C. § 135(b)(1)

According to 35 U.S.C. § 135(b)(1), "[a] claim which is the same as, or for the same or substantially the same subject matter as, a claim of an issued patent may not be made in any application unless such a claim is made prior to one year from the date on which the patent was granted." Thus, a claim must be identified or presented prior to one year from the date of patent issue.

The '207 patent on issued September 18, 2001, and the '336 patent issued October 16, 2001. As Applicants submit that the two Spear and Montgomery patents are directed to the same or substantially the same patentable invention for purposes of the interference, September 18, 2002 has been designated as the one year period of 35 U.S.C. § 135(b) for purposes of this Request for Interference.[16]

Claims 27-38, 81-86 and 187-196 of the captioned application have been identified as corresponding either exactly or substantially to the proposed count and were pending prior to the filing date of this Request for Interference, *i.e.* April 25, 2002. In addition, all of the claims of the '207 and '336 patents have been identified as corresponding either exactly or substantially to the proposed count. Accordingly, since all of Applicants' claims designated as corresponding to the proposed count were of record prior to April 25, 2002, which is prior to September 18, 2002, Applicants were claiming substantially the same subject matter within one year of the

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[16]Obviously, by designating September 18, 2001 as the one year period of 35 U.S.C. § 135(b)(1), the one year period for the '336 patent, issued October 16, 2001, is also met.

issuance of the two Spear and Montgomery patents, thereby satisfying the requirements of § 135(b)(1).

B. 35 U.S.C. § 135(b)(2)

35 U.S.C. § 135(b)(2) took effect on November 29, 2000 and is only applicable to applications filed on or after that date. Since the captioned application was filed on June 29, 1999, and no CPA's were filed on or after November 29, 2000, the requirements of this section are inapplicable.

Conclusion

As provided above, the requirements of 37 C.F.R. § 1.607 have been satisfied. Accordingly, it is respectfully requested that an interference be declared between the captioned application and the two Spear and Montgomery patents. Early notice to that effect is earnestly solicited.

Respectfully submitted,

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